K011457

MAY 2 3 2001

510(k) Summary

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

Submitter's Name and Address

Aloka Co., Ltd.
10 Fairfield Boulevard
Wallingford, CT 06492

Contact's Name, Title, Address and Telephone Number

Kelvin Burroughs
Regulatory Affairs/Quality Assurance Coordinator
Aloka Co., Ltd.
10 Fairfield Boulevard
Wallingford, CT 06492
(203) 269-5088

Device Proprietary Name

Aloka SSD-5500 Diagnostic Ultrasound System with KI and A-SMA

Device Common Name

Diagnostic Ultrasound System

Classification

The charts below list the Regulatory Class and Device Codes.

Subject	Description
Regulatory Class	Class II
Review Category	Tier II

Code	Description	Regulation
90 ITX	Transducer, Ultrasonic, Diagnostic	892.1570
90 IYN	Ultrasonic, Pulsed Doppler Imaging System	892.1550
90 IYO	Ultrasonic, Pulsed Echo Imaging System and Accessories	892.1560

Continued on next page

510(k) Summary, Continued

Identification of predicate devices

Aloka SSD-5500 Diagnostic Ultrasound System – K992663
Hewlett-Packard Sonos 2500 – K964309

Device Description

A-SMA, which means Automated-Segmental Motion Analysis, will combine two major breakthroughs in the ultrasound industry, Kinetic Imaging (KI) and Acoustic Quantification (AQ). The A-SMA concept comprises the following methods; differentiation of the cardiac chamber from its surrounding muscle as in KI, division of the chamber into several regions, measurement of the area of each region, and computation the rate of change of each region as in AQ.

Intended Use

The Automated-Segmented Motion Analysis (A-SMA) uses Kinetic Imaging Technology and Quantitative Fractional Area Change to produce more reliable data for a trained medical professional to determine cardiac wall motion dysfunction.

Safety Considerations

The Aloka SSD-5500 with KI and A-SMA is designed and manufactured to the following standards and regulations:

- FDA's Quality Systems Regulations
- ISO 9001
- ISO 10993
- NEMA UD2 Acoustic Output Measurement Standards
- AIUM 1998 Acoustic Output Labeling Standards
- IEC 60601-1-2
- IEC 60601-2-37
- UL – 544

There are no 514-performance standards for diagnostic ultrasound equipment.

Removed and replaced 05/07/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2001

Aloka Co., Ltd.
% Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services NA Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K011457
Trade Name: SSD-5500 Diagnostic Ultrasound System with Kinetic Imaging (KI) and Automated Segment Motion Analysis (A-SMA)
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: May 9, 2001
Received: May 11, 2001

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for use with the SSD-5500 Diagnostic Ultrasound System with Kinetic Imaging (KI) and Automated Segment Motion Analysis (A-SMA), as described in your premarket notification:

Transducer Model Number:

UST-5280-5
UST-5086-2.5

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good

Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Diagnostic Ultrasound Indications for Use Form

System/Transducer	System
Model	SSD-5500 with KI and A-SMA
510(k) Number	K992663

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		N/See Below	
Transesophageal		P	P	P	P	P	P		N/See Below	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E;

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD, B/A-SMA.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011457

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5280-5
510(k) Number	K002784

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	**Modes of operation**									
	A	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Amplitude Doppler**	**Color Velocity Imaging**	**Combined (specify)**	**Other (specify)**
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P	P	P	P	P	P		N/See Below	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E;

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011457

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5086-2.5
510(k) Number	K992663

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		N/See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E;

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Hagen

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011457

Prescription Use (Per 21 CFR 801.109)